

What Is Claimed Is:

1 1. A method for differentiating between allergic rhinitis, upper respiratory tract viral  
2 infection and bacterial sinusitis, which comprises measuring a sample of a patient's nasal  
3 secretion for pH, protein concentration, nitrite concentration, leukocyte esterase activity,  
4 and eosinophil counts or TAME esterase activity or both, such that a scoring system is  
5 developed through a combination of:

6 (a) a pH between about 7.5 and 9, a moderately strong presence of protein, nitrite or  
7 leukocyte esterase, and low or absent eosinophil counts or TAME esterase activity is  
8 indicative of bacterial sinusitis without an allergic condition;

9 (b) a pH between about 5 and 7, little or no protein, little or no nitrite, little or no  
10 leukocyte esterase activity, and moderate to significant TAME esterase activity or  
11 moderate to high eosinophil counts is indicative of allergic rhinitis; and

12 (c) a pH between about 5 and 7, little or no protein, low concentration or a trace of  
13 nitrite or a trace of leukocyte esterase or both and low or absent eosinophil counts or low  
14 or absent TAME esterase activity indicates an upper respiratory tract viral infection;  
15 wherein said method comprises deposition by a patient of a nasal secretion sample within a  
16 collection apparatus adapted for receipt of said sample for concurrent or subsequent  
17 contact with reagents indicative of the pH, protein, nitrite, leukocyte esterase, eosinophil or  
18 TAME esterase concentrations.

1 2. The method of claim 1 wherein said collection apparatus comprises a sealable  
2 container for said nasal secretion sample.

1 3. The method of claim 2 wherein said container further comprises a unitary reagent  
2 test strip.

1 4. The method of claim 2 wherein a reagent test strip is inserted into said container to  
2 obtain a differential diagnostic readout.

1 5. The method according to claim 4 wherein said container comprises a series of holes  
2 disposed so as to permit air blown into said container to escape, without at the same time  
3 permitting said nasal secretion to escape.

1001555-121001

1 6. The method according to claim 5 wherein said container comprises a means for  
2 sealing said series of holes to prevent nasal secretion from oozing from said container.

1 7. The method according to claim 6 wherein said container comprises a means for  
2 associating a particular nasal secretion sample with a particular patient.

1 8. The method according to claim 1 wherein said pH, protein concentration, nitrite  
2 concentration, and leukocyte esterase activities are each assigned a score, such that upon  
3 analysis of summed scores for these measures, a clear clustering of patient data  
4 measurements occurs such that summed data from patients suffering from allergic rhinitis  
5 is substantially separated from patient data from patients afflicted with viral respiratory  
6 infection and wherein data from such patients is substantially separated from patients  
7 afflicted with sinusitis.

1 9. A device for differentiating between allergic rhinitis, upper respiratory tract viral  
2 infection and bacterial sinusitis, comprising a support upon which is fixed discrete  
3 indicators of pH, protein content, nitrite content, leukocyte esterase activity, and eosinophil  
4 content or TAME esterase or both, of a sample with which said fixed discrete indicators  
5 are contacted, wherein said support further comprises a means for collecting said nasal  
6 secretion while minimizing contact of said nasal secretion with personnel using said  
7 collection device.

1 10. The device according to claim 9 configured as a reagent test strip or reagent pads  
2 integral to a nasal secretion collection device.

1 11. The device according to claim 9 comprising an immobilized eosinophil specific  
2 protein or an indicator of TAME esterase activity.

1 12. The device according to claim 10 wherein said reagent test strip or reagent pads are  
2 compartmentalized from each other such that cross contamination between adjacent  
3 reagents is minimized or eliminated completely.

10015525 121301

1 13. The device according to claim 9 wherein said nasal secretion is collected in said  
2 collection device, and wherein contact of the nasal secretion with said reagent test strip or  
3 reagent pads is prevented by a removable barrier means such that the time of contact of  
4 said nasal secretion with said reagent test strip or reagent pads may be controlled.

1 14. The device according to claim 9 wherein said protein is selected from the group  
2 consisting of eosinophil major basic protein, eosinophil cationic protein, eosinophil derived  
3 neurotoxin, eosinophil peroxidase, and mixtures thereof.

1 15. The device according to claim 14 wherein said protein is bound to a labeled or  
2 unlabeled avidin, biotin, or antibody.

1 16. The device according to claim 14 comprising an immobilized antibody specific to  
2 an eosinophil specific antigen.

1 17. The device according to claim 16 wherein said antibody is specific to a protein  
2 selected from the group consisting of eosinophil major basic protein, eosinophil cationic  
3 protein, eosinophil derived neurotoxin, eosinophil peroxidase, and mixtures thereof.

1 18. The device according to claim 17 comprising an immobilized substrate which upon  
2 contact with an eosinophil specific enzyme or one or more enzymes found in secretions of  
3 patients with allergic rhinitis is converted to a detectable reaction product.

1 19. The device according to claim 18 wherein said enzymes found in secretions of  
2 patients with allergic rhinitis ~~reacts~~ with TAME, tosyl-Arg-paranitrophenyl ester, or  
3 paranitroaniline, Z-Arg-paranitroaniline, B-Z-Arg-paranitroaniline.

1 20. The device according to claim 19 wherein said substrate is a chromogenic  
2 substrate.

1 21. A device for collecting nasal secretions which comprises a sealable container into  
2 which a patient may blow their nose, or into which a child's nose may be wiped or  
3 squeezed to obtain nasal secretion, wherein said container comprises a series of holes

10015525 4:30 PM

4 disposed so as to permit air blown into said container to escape, without at the same time  
5 permitting said nasal secretion to escape.

1 22. The device according to claim 21 wherein said container comprises a means for  
2 sealing said series of holes to prevent nasal secretion from oozing from said container.

1 23. The device according to claim 22 wherein said container comprises a means for  
2 associating a particular nasal secretion sample with a particular patient.

1 24. The device according to claim 21 wherein said sealable container is sealed by  
2 means of a zip-lock strip.

1 25. The device according to claim 21 wherein said sealable container further comprises  
2 a pre-crimped patient label disposed so as to be folded over with an adhesive strip to  
3 ensure retention of nasal secretions within said container.

1 26. The device according to claim 21 wherein said device is colored or opaque.

1 27. The device according to claim 26 wherein said device may be made translucent or  
2 colorless by peeling a colored or opaque coating from the exterior of said collection  
3 device.

1 28. The device according to claim 21 wherein said device is manufactured or  
2 distributed as a releasably joined plurality of said collection devices.

1 29. A method for differential diagnosis of bacterial sinusitis, allergic rhinitis and upper  
2 respiratory tract viral infection comprising the steps of:

- 3 (a) collecting a patient's nasal secretions within a container; and  
4 (b) contacting said nasal secretions in said container with reagents which provide a  
5 differential readout depending on whether said patient is afflicted with sinusitis,  
6 upper respiratory tract viral infection or allergic rhinitis.

10015525 "121301"

1 30. The method according to claim 29 wherein allergic rhinitis is confirmed by means of  
2 contacting said nasal secretions with a reagent which provides a detectable signal if  
3 TAME esterase or eosinophils are present in said secretion.

1 31. A kit for differential diagnosis of bacterial sinusitis, allergic rhinitis and upper  
2 respiratory tract viral infection wherein said kit comprises:  
3 (a) a means for collecting a patient's nasal secretions within a container;  
4 (b) a means for providing a differential readout upon contact with said nasal secretion,  
5 depending on whether said patient is afflicted with sinusitis, upper respiratory tract  
6 viral infection or allergic rhinitis.

10015525 424304